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EXAMINER

NGO, LIEN M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3727

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary

Application No.

08/944,234

Applicant(s)

KUNZLER ET AL.

Examiner

LIEN TM NGO

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 and 52-125 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 13-50 and 52-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 12 April 2002 is: a) ☐ approved b) ☒ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Drawings

1. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 12/4/02 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(a)(6) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support or mention to the description of the new adding figs. 5-7.

Specification

2. The amendment filed 12/4/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the disclosure of new adding figs. 5-7 (paragraphs 10, 40-46), the method of milling a vertebral body using the present invention drill head (paragraph 47-53 and the abstract).

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The original drawings does not show every feature of the invention specified in the claims. For example, the predetermined shape

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of an endoprosthesis (claims 18), the "concave-convex shape" of an endoprosthesis (claim 24), the "surface contour in one of the adjacent vertebral bodies" (claims 24, 41, 47, 67, 82, 97, 114, 119, 120, 121), the "slot" (claims 29, 72, 86, 103), the "width of the insert" (claims 41, 49), the milling surface is "parallel to a receiving surface" (claims 49, 85, 102), the steps of the method claims 62-66, the "two predetermined surface contours" (claims 77, 93, 110,).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25-125 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For example:

In claims 25, 41, 52, 67, 82, 97, 114, "at least one milling surface";

claims 29, 86, 103 "a slot";

claims 37, "a smooth surface";

claims 47, "at least one broad milling surface";

claim 48, "said drive...end plates"

claim 49, "said milling surface...by said device";

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claim 53, "outwardly facing first and second milling surfaces";
claim 58, "said bearing surface is smooth";
claims 62-66, the steps of claimed methods;
claim 68, "first ad second milling surfaces";
claims 36, 77, 93, 110 "at least two milling surfaces ... and end plate";
claims 37, 78, 82, "a smooth surface";
claim 98, "at least two milling surfaces";
claims 102, 119, "at least...vertebral bodies";
claim 120, "a broad milling surface";
claim 121, "at least one top milling surface".

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 36, 50, 53, 54, 77, 93-96, 98, 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 36, 50, 53, 54, 77, 93-96, 98 and 99, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where

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broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 36, 77, 93 and 98 recite the broad recitation "at least one milling surface", and the claim also recite "at least two milling surfaces" which is the narrower statement of the range/limitation.

It also, the claims are indefinite and confusing whether "at least two milling surfaces" is the same with "at least one milling surface" as defined in their independent claims.

Claims 50 and 53 are indefinite because the claims define two milling surfaces while their independent claim 59 which defines a milling surface.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 5-7, 13-61 and 67-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheicher (4,197,645).

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In regard to claims 1-3, 5-7, and 13-24, Scheicher discloses, in figs.1-4 and 13-18, a milling apparatus or a device for preparing a space in human bone to receive an implant comprising head and bone drill comprising: a drill head 11, a rotary form cutter 5, a drive means 40, elongate housing 3, said form cutter has a convex shape, a groove, and provided with a beveled gearing surface 37, the height of profile of the form cutter is approximately 9 mm, as disclosed in col.17, line 56, said drive means having a pinion gear 39, and said cutter having a support shaft 8 which forms an angle approximately 96 degrees to the drive means 40. (angle approximately 96 degrees which generally could be 90 degrees).

The statement of intended use of the device for preparing a space in a human spine to receive and insert between adjacent vertebral bodies has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Scheicher, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In regard to claims 25-61 and 67-125, Scheicher device disclose all limitations as claimed.

Response to Arguments

10. Applicant's arguments filed 12/4/02 have been fully considered but they are not persuasive.

In response to applicant's argument that no new matter arises from the amended specification. However, that is not found convincing, because the added material in the

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specification which is not supported by the original disclosure is as follows: the disclosure of new adding figs. 5-7 (paragraphs 10, 40-46), and the method of milling a vertebral body using the present invention drill head (paragraph 47-53 and the abstract). Applicant argues that no new matter arises because in the original specification, page 3, "U.S. patent No. 5,674,296, incorporated herein by reference, provides a vertebral disc endoprosthesis ..." and page 5, "the convaval- convex shape of the endoprosthesis which is the subject of U.S. patent No. 5,674,296". However, the method of using a milling device for repairing the disc space between adjacent vertebrae to receive an endoprosthesis is not in patent 5,674,296, and the original specification does not disclose how is the endoprosthesis installed in the vertebrae as shown in the new figs. 5-7.

In response to applicant's request to withdraw the drawing objections by providing new figures 4-7 in order to support illustrating of the claimed inventions. However, that is not found persuasive because the original specification does not describe to the new figures, and the original drawings does not show every feature of the invention specified in the claims (see drawing objections above). Moreover, the new figures 4-7 are copies from figs. 1-4 of the patent 5,674,296 which does not teach a milling device using for preparing the disc space between adjacent vertebrae to receive an endoprosthesis between, and the original drawing in the present application does not show an endoprosthesis received between adjacent vertebrae and the milling device works to prepare the disc space between the adjacent vertebrae. Therefore, the new

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drawing introduces new matter and the original drawing does not show every feature of the invention specified in the claims as specified in above drawing objections.

In response to applicant's traverse to the 35 U.S.C 112 rejections, first paragraph, however, that is not persuasive

In respect to claims 25, 41, 52, 67, 82, 97, 114, "at least one milling surface" is not supported in the specification because no where in the original specification sets forth that the cutter has more than one milling surface, only on page 5, lines 9-10, says that "the illustrated form cutter 29 has a convex milling surface 42, and line 17, "the form cutter further includes an onwardly extending edge 44 about it perimeter". Therefore, the present invention comprises only one milling surface with extending edge, and "at least one milling surface" or more than one milling surface has not been intended to claim or disclosed in the original specification.

claims 29, 86, 103, the housing disposed at the distal end of the shaft portion has "a slot" configured... is not support in the specification. Applicant traverses that in amended fig.2 which shows slot 46. However, the slot 46 is not disposed in housing 20 at the distal end of the shaft portion.

claims 37, "a smooth surface" is not supported in the original specification. Although each of figs 1-3 illustrates the surface 31 of the housing 20 being flat and smooth, but it is submitted that one ordinary skill in the art would appreciate that it is advantageous to provide a rough surface 31 to permit the housing to stay in a stable position as it contact to a vertebrae during milling the bone.

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claims 47, as the same reason to above “ at least one broad milling surface” or more than one broad milling surface is not supported in the original specification.

claim 48, “said drive...end plates”and claim 49, “said milling surface...by said device” are not supported in the original specification paragraph 25-26.

claim 53, “outwardly facing first and second milling surfaces”, as similar examiner’s argument above that present invention has only one milling surfaces.

claim 58, “said bearing surface is smooth”, see examiner’s argument as claim 37

claims 62-66, the steps of claimed methods are not support in the original specification.

claim 68, “first ad second milling surfaces”, see examiner’s argument as claim 25

claims 36, 77, 93, 110 “at least two milling surfaces ... and end plate”; see examiner’s argument as claim 25.

claims 37, 78, 82, “a smooth surface”; see examiner’s argument as claim 37.

claim 98, “at least two milling surfaces”, see examiner’s argument as claim 25.

claims 102, 119, “at least...vertebral bodies”, see examiner’s argument as claim 25 and 48.

claim 120, “a broad milling surface” and “said form cutter is moved by said drive means in a plane generally parallel to...” are not supported in original specification.

claim 121, “at least one top milling surface”, see examiner’s argument as claim 25.

In response to applicant’s traverse to claim rejection-35 U.S.C 112, second paragraph, Claims 36, 50, 53, 54, 77, 93-96, 98 and 99 are indefinite as pointed out in the rejection above.

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In response to applicant's argument that the Scheicher does not disclose the limitations of the claims as applicant pointed out in the response, page 27, lines 13-20 and page 28, lines 1-12. However, that is not found convincing, because Scheicher discloses in fig. 1-4 and 13-18, a device comprising a drill head 5 (a, b and c) wherein the maximum height of the profile of the form cutter is prefer about 2.8-6 mm (distances A,B and C in fig.3, see col.17, lines 52-57) which meet limitation of claim 20. This profile height of Scheicher device is capable of milling a space between adjacent vertebrae to received an insert if one desires to do so. The form cutter has at least one milling surface being convex (see figs. 2, 5 and 23) and a support shaft 8 which form angle about 90 degrees to the drive means 40. Examiner notes that claim 22 requires the angle being approximately 96 degrees and it is clear to one ordinary skill in the art would consider an angle approximately 96 degrees being generally about 90 degrees.

The statement of intended use of the device for preparing a space in a human spine to receive and insert between adjacent vertebral bodies has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Scheicher, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

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Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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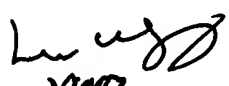
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lien Ngo whose telephone number is (703) 305-0294. The examiner can normally be reached Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful. The examiner's supervisor, Lee Young, can be reached at (703)308-2572. The Group FAX number is (703) 305-3579.

Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist at (703) 308-1148.


Lien Ngo

January 29, 2003


LEEYOUNG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700